Popularising Generic Medicines

383. SHRI C. PERUMAL: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is proposed to popularize generic medicines without brand names;

(b) if so, how the problem of spurious medicines will be tackled;

(c) whether it is proposed to provide quality certification for medicines on the lines of ISI mark;

(d) if so, the details thereof; and

(e) if not, the reasons therefor?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) In order to popularize generic medicines without brand name the Government purchases of drugs are generally on generic names. Also, the labeling provisions under Drugs and Cometics Rules had been amended to provide that the generic name of the product should appear in more conspicuous manner than the brand name.

(b) Problem of spurious drug may span both branded as well as generic drug for which detailed guidelines have been provided to all State Drug Control Authorities who are the enforcing authorities to monitor quality of drugs. Strict penalties have been prescribed under the Drugs and Cosmetics Act for persons found indulging in manufacture or sale of spurious drugs. Also, the Government of India is providing substantial assistance to State governments under a capacity building project to augment drug-testing capacities of States laboratories so that any suspected drug can be speedily analyzed.

(c) to (e) The standards of drugs are prescribed under the Drugs and Cosmetics Act and rely on pharmacopoeial monographs which prescribe detailed quality specifications. The Bureau of Indian Standards (BIS) does not prescribe quality specifications for drugs.

The requirements of Good Manufacturing Practices (GMPs) prescribed under D&C Rules are required to be adhered to by all drug-manufacturing units in the country. Therefore, there is no separate certification for medicines on the line of ISI marks.